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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,863	06/13/2006	Per Holm	20481/1206898-US1	9762

7278 7590 03/31/2010

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EXAMINER	
POLANSKY, GREGG	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
03/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/569,863	HOLM ET AL.	
	Examiner	Art Unit	
	GREGG POLANSKY	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,16-29,31-34,36-44 and 51-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,16-29,31-34,36-44 and 51-57* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/09/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. By way of the submission filed on 12/31/2009, Applicants have canceled Claims 11-15, amended Claims 1, 5-10, 16, and 42, added Claim 57, and presented arguments in response to the Office action mailed 10/08/2009.

2. Applicants' Information Disclosure Statement, filed 12/09/2009, is acknowledged and has been reviewed. Foreign patent document citation number 7 has been considered previously.

3. Applicants' arguments with regard to appropriateness of Claims 38 and 39 being previously withdrawn by the Examiner as not reading on the elected species is convincing. Accordingly, Claims 38 and 39 are no longer withdrawn and have been examined as indicated below.

4. Claims 1, 3-10, 16-29, 31-34, 36-44 and 51-57 are pending and presently under consideration.

5. Applicants' arguments have been fully considered and are persuasive in part. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

6. It is noted that although Claim 10 has been amended by the Applicant, the status identifier recites "Previously Presented" instead of "Currently amended".

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 3-10, 16-29, 31-34, 36-44, and 51-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the active ingredient" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. The "active ingredient" is not defined by the claim.

Claims 3-5 recite the limitation "the active ingredient" and/or "the vehicle" of Claim 1. There is insufficient antecedent basis for this limitation in the claim. The "active ingredient" and "vehicle" are not defined by the claims.

Claim 56 recites the limitation "the active ingredient" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. The "active ingredient" is not defined by the claim.

Claim 1, as presently amended, recites a "A solid pharmaceutical composition comprising tacrolimus in polyethylene glycol having an average molecular weight of at least 1500 and a poloxamer on a solid carrier". It is unclear whether the composition

comprises: (tacrolimus in polyethylene glycol) combined with (a poloxamer on a solid carrier); or, (tacrolimus in polyethylene and a poloxamer) on a solid carrier. Thus, the metes and bounds of the claim are unclear.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 3-10, 16-29, 31-34, 36-44, 55 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **New Matter** rejection.

Claim 1, as presently amended, recites a "A solid pharmaceutical composition comprising tacrolimus in polyethylene glycol having an average molecular weight of at least 1500 and a poloxamer on a solid carrier". The claim can reasonably be interpreted as being drawn to a composition comprising tacrolimus in polyethylene glycol, in combination with a poloxamer on a solid carrier. This is not supported by the disclosure as originally filed.

The Specification as originally filed has adequate written description for a composition comprising tacrolimus dissolved or dispersed in polyethylene glycol,

combined with a poloxamer, and said combination applied on a solid carrier to obtain the solid pharmaceutical composition.

The proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). See MPEP § 2163.06 through § 2163.07 for a more detailed discussion of the written description requirement and its relationship to new matter. The claims as filed in the original specification are part of the disclosure and, therefore, if an application as originally filed contains a claim disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985). Thus, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1, 3-10, 16-20, 24-26, 31-34, 38-44, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koretke et al. (WO 01/95939 A1; cited and provided by Applicants), in view of "Tacrolimus (Systemic)" (Drugs.com; previously cited; hereinafter referred to as "Drugs.com").

Koretke et al. teach a fast release solid dispersion pharmaceutical composition of an active compound, poloxamer 188 and polyethylene glycol having a molecular weight of 6000 (PEG 6000). See Abstract and pages 9-10, claims 1, 8, and 9-11. The compositions taught by Koretke et al. can be formulated as capsules. Whereas the capsules are made by filing capsules with the composition in the form of a melt, the empty (gelatin) capsule serves as a solid carrier. See page 7, lines 19-24. The ratio of polyethylene glycol to poloxamer taught by Koretke et al. is in the range of 3:1 to 49:1. Koretke et al. teach solid dispersion compositions comprising about 0.1% to about 20% active agent. See page 9, claim 4. The reference teaches the disclosed fast release solid dispersion composition increases the bioavailability of water insoluble drugs without the need for using organic solvents. See page 2, lines 20-22. Solid dispersion formulations comprise a drug dissolved or dispersed in a polymer. See page 1, lines 1-2. Thus, the solid dispersion compositions taught by Koretke et al. comprise an active

ingredient in the form of a solid dispersion and/or a solid solution with the composition polymer(s). The poloxamer and polyethylene glycol of the composition are pharmaceutically acceptable excipients. The compositions of Koretke et al. are suitable for oral administration. See page 10, claim 12. Polyethylene glycol is a polyether glycol (a hydrophilic oily material), thus satisfying the requirements of instant Claims 33 and 34. The reference teaches additional agents may be added to the composition. These agents include, for example, various cellulosic polymers, acacia, sodium alginate, and starch. See page 6, lines 9-24. These agents can act as, for example, suspending agents, flavoring agents, release modifying agents, and stabilizing agents. Koretke et al. teach the use of aminoalkyl methacrylate copolymer E (i.e., EUDRAGIT E) as a "gastric coating base" (i.e., release modifying agent). Hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose acetate succinate, cellulose acetate phthalate, methacrylic copolymer LD and S and ethylcellulose (as required by instant Claim 32) are also taught by the reference. See page 6, lines 9-24. The use of, *inter alia*, ethylcellulose as an enteric coating agent (i.e., release modifying agent) is well known in the art. For example, see Yang et al. (International Journal of Pharmaceutics, 1992, Vol. 86(2-3) pp. 247-257, Abstract only; provided for evidentiary purposes only).

Poloxamer 188 in the formulation of Koretke et al. (supra) satisfies the requirement of instant Claim 38 (i.e., a poloxamers). EUDRAGIT E and other methacrylic polymers (supra) satisfy the requirements of instant Claims 38 and 39.

The limitations of Claims 40 and 41 are met by at least Koretke et al. teaching aminoalkyl methacrylate copolymer E as a gastric coating and

hydroxypropylmethylcellulose acetate succinate, cellulose acetate phthalate, methacrylic copolymer LD and S (*supra*), all of which are known to be used as pharmaceutical coating agents (the water solubility of each agent is pH-dependent as instantly disclosed).

Koretke et al. teach compositions useful for increasing the bioavailability of water insoluble drugs. The reference, does not specifically teach compositions comprising tacrolimus.

Drugs.com is teaches tacrolimus being practically insoluble in water, and that tacrolimus has "[r]apid, variable, and incomplete [absorption] from the gastrointestinal tract" and a mean oral bioavailability of 27%, with a range of 5-65%. See Solubility, at page 2 and Absorption at page 3.

The need for a tacrolimus composition having improved bioavailability would have been obvious to one of ordinary skill in the art at the time of the invention because Drugs.com teaches the poor bioavailability of tacrolimus. Since Koretke et al. teach compositions useful for increasing the bioavailability of water insoluble drugs it would have been obvious to the artisan to utilize the methods of Koretke et al. to produce a more bioavailable tacrolimus composition with a reasonable expectation of success.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess

the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). Also see *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound "inherently" anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate).

In the instant case, absent evidence to the contrary, it would be expected that a composition taught by Koretke et al. comprising tacrolimus would naturally meet the dissolution requirements of the instant claims. Additionally, one would expect, absent evidence to the contrary, that the tacrolimus composition would have a similar bioequivalence to the formulation of the instant methods (instant Claims 42-44).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re*

Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. Claims 1, 3-10, 16-29, 31-34, 36-44 and 51-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holm et al. (WO 03/004001 A1, cited by Applicants), in view of "Tacrolimus (Systemic)" (Drugs.com; previously cited; hereinafter referred to as "Drugs.com").

Holm et al. teach "[a] process for the preparation of a particulate material by a controlled agglomeration method, i.e. a method that enables a controlled growth in particle size. The method is especially suitable for use in the preparation of pharmaceutical compositions containing a therapeutically and/or prophylactically active substance which has a relatively low aqueous solubility..." See Abstract. Holm et al. teach "very promising results with respect to bioavailability when [the disclosed formulation process] is employed for the preparation of particulate material containing an active substance with a very low aqueous solubility." See lines 1-8, at page 12. The reference teaches the advantageous use of the disclosed composition methods for formulating drugs having poor water solubility and low bioavailability and discloses, *inter*

alia, cyclosporine, erythromycin, and clarithromycin as a candidate drugs. See, page 13, line 19; page 16, 3rd from bottom of Table 1; and page 19, 7th from bottom of Table 2. All three of these drugs, as well as tacrolimus, are macrolides.

"The particulate material obtained by a process [disclosed by Holm et al.] is especially suitable for further processing into tablets." Formulating the tablets to have particular release characteristics is also disclosed. See lines 4-13, at page 27. The reference teaches the particulate material (*supra*) having a geometric weight mean diameter of from 20 µm to 2000 µm. See lines 6-17, at page 28. The process taught by Holm et al. involves melting the carrier(s) (e.g., polyethylene glycol 6000 (PEG 6000) and poloxamer 188), dissolving or dispersing the drug in the melt, and spraying the resulting composition on to a pharmaceutically acceptable excipient having a relatively high particle density. Suitable excipients include fillers, diluents, disintegrants, binders, and lubricants. See page 2, lines 1-29; page 21, 3rd paragraph; and the paragraph bridging pages 21-21. Lactose and microcrystalline cellulose are exemplified. Holm et al. exemplify particulate preparations, tablets of the preparations, and the resulting improvements in drug bioavailability. See Examples 1-6, at pages 31-56. For example, see Example 4 which discloses tablets of a particulate formulation (Treatment B) comprising a drug, PEG 6000, poloxamer 188, and Avicel® PH 101 (microcrystalline cellulose). The PEG 6000 and poloxamer 188 are melted by heating to 75° C. The drug is dissolved in the melt, which is then sprayed onto the microcrystalline cellulose and allowed to cool. The resulting granulate is used to form tablets. The process does not use organic solvents. The ratio of PEG 6000 to poloxamer 188 is about 2.4:1.

Exemplified drug concentrations in Example 4 range from about 1 to 5 percent. With respect to the instantly claimed ratio of polyethylene glycols to poloxamers and the instantly claimed drug concentration, it is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(11).

Colloidal silica, magnesium aluminosilicate and/or magnesium aluminometasilicate may be used as lubricants. See lines 19-23, at page 22; and lines 25-26, at page 28. Additional additives taught by Holm et al. include, coloring agents, taste-masking agents, pH-adjusting agents, solubilizing agents, stabilizing agents, wetting agents, surface active agents, antioxidants, and release modifying agents. See page 22, lines 25-28. The use of enteric coatings is taught by Holm et al. See page 26, lines 12-14. Hydroxypropyl methylcellulose is among the agents disclosed as suitable coating materials. See page 26, lines 16-21.

Drugs.com is provided to further demonstrate prior art knowledge of tacrolimus being practically insoluble in water, and that tacrolimus has "[r]apid, variable, and incomplete [absorption] from the gastrointestinal tract" and a mean oral bioavailability of 27%, with a range of 5-65%. See Solubility, at page 2 and Absorption at page 3.

Holm et al. teaches or suggests all of the limitations of the instant claims, with the exception of tacrolimus as the active drug. Drugs.com teaches the low aqueous solubility and oral bioavailability of tacrolimus. Holm et al. teach compositions of various macrolide drugs. It would have been obvious to one of ordinary skill in the art (e.g.,

pharmaceuticals) at the time of the invention to substitute one known macrolide having low aqueous solubility and bioavailability, with another macrolide having low aqueous solubility and bioavailability, and have a reasonable expectation of success. Motivation would have come from the desire to improve the release profile/bioavailability of formulations of tacrolimus.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). Also see *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound "inherently" anticipated the claimed hemihydrate form of the compound because practicing the

process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate).

In the instant case, absent evidence to the contrary, it would be expected that the release rates and bioavailability of tacrolimus formulated according to methods taught by Holm et al., would be the same as those recited by the instant claims.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 3-11, 13-29, 31-34, 36, 37, 40-44 and 51-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-10, 20-25, 27-29, 31-37, 40-44, 51 and 52 of copending Application No. 10/569862. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to similar pharmaceutical compositions of tacrolimus and methods of preparation of said compositions. The open language of the instant claims allows for the inclusion of additional constituents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

16. Claims 1, 3-10, 16-29, 31-34, 36-44 and 51-57 are rejected.

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is

(571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614